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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/759,430	01/12/2001	Lee R. Bolduc	105-C1	1423

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EXAMINER

EREZO, DARWIN P

ART UNIT PAPER NUMBER

3731

DATE MAILED: 09/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/759,430

Applicant(s)

BOLDUC ET AL.

Examiner

Darwin P. Erez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-30 and 36-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14, 16, 17, 19-30, 36, 38, 41-60 and 62-72 is/are rejected.
- 7) ☒ Claim(s) 15, 18, 37, 39, 40 and 61 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 14, 16, 17, 19-30, 36, 38, 41-60 and 62-72 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,234,447 to Kaster et al.

Kaster teaches a method for an end-to-side anastomosis comprising the steps of providing an anastomosis device (**10,12**) having a plurality of openings (or slots defined in the core unit **14** having openings to secure the staple **12** within the sleeve **12**; also viewed as the means for holding the tissue securing elements); and a plurality of tissue securing elements having a first end a second end (**44,43**) and capable of being biased from an unbiased configuration to a biased configuration; holding the plurality of tissue securing elements in the biased configuration (Fig. 14); inserting the first end through the second hollow tissue (Fig. 17); permitting the plurality of the tissue securing element to move from the biased configuration to the unbiased configuration (transitioning from Fig. 17-19); wherein the first end of the tissue securing elements contact the inner surface of the second hollow tissue and the second end of the tissue securing element contact the outer surface of the second hollow tissue (end of transition shown in Fig. 19), wherein the first end of the tissue securing elements are permitted to assume the unbiased configuration prior to the second end (Fig. 17); wherein the anastomosis is

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formed between a first blood vessel and a second blood vessel (which could be the aorta since the aorta is blood vessel); wherein both the first and second hollow tissues are compressed; wherein the first hollow tissue is everted prior to insertion to about 90 degrees, more or less (Fig. 15 and depending on the base of the angle); wherein the distal end of the first hollow tissue is compressed against the outer surface of the second hollow tissue (Fig. 17); wherein the first end of the tissue securing elements is inserted from an exterior surface toward the interior surface (since the tissue is everted; Fig. 15); wherein the device further comprises a hub having a bore (the diameter of element **46**) that receives the first hollow tissue; wherein the device comprises a body (element **46** can also be viewed as a body/sleeve); wherein the anastomosis device or the delivery device is removed after delivering the securing elements, wherein the anastomosis device comprises a plunger or mandrel **16** for delivering the securing elements; and wherein the anastomosis device has a bore and the plurality of openings communicate with each other via the bore (see Fig. 5).

Allowable Subject Matter

3. Claims 15, 18, 37, 39, 40 and 61 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Terminal Disclaimer

4. The terminal disclaimer filed on 6/26/06 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US

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7,056,326 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Response to Arguments

5. Applicant's arguments filed 6/26/06 have been fully considered but they are not persuasive.

The applicant argued that Kaster fails to teach a securing element comprised of a material that is capable of being biased from an unbiased configuration to a biased configuration. However, this is not persuasive because Kaster does teach a securing element, or staple **12**, that is made of stainless steel, which is capable of being biased to an unbiased configuration by the stapler or delivery device. The claim limitation merely requires that the securing element is comprised of a material that is capable of being biased or unbiased and it does not preclude any additional structure that helps or perform said biasing action.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezzo whose telephone number is (571) 272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Darwin P. Erezzo
Examiner
Art Unit 3731

de


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
2/5/06